

### REMARKS

Applicants have amended claims 1, 2, 9-11, 19, 22-24 and 26. The amendments are supported by the specification as originally filed at page 3, lines 1-2; page 15, lines 6-10; and page 17, lines 13-18. No new matter has been added to the claims. Claims 1 through 26 remain pending:

As requested by the Office, a copy of Information Disclosure Statement filed April 2, 2001, is enclosed.

#### 35 U.S.C. § 102 Rejections Based on Richter

Claims 1, 4-6 and 14-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Richter (U.S. Patent No. 6,315,794). Applicants respectfully traverse this rejection on the following grounds. First, while the Examiner characterizes a stent to be a component **of** a catheter, it is respectfully submitted that a stent is instead commonly considered to comprise a device that is delivered **by** or **on** a catheter. Accordingly, a stent is described in the specification at page 2, lines 6-14 as a device separate and apart from the catheter by which it is delivered. As a consequence, it is respectfully submitted that the reference upon which the Examiner relies cannot reasonably be considered to be anticipatory in view of the fact that it is directed to a very different device and structure.

Moreover, the claims have been amended to emphasize a second critical distinction with regard to this reference to the extent that the Richter is directed to the

marking of metallic stents (col 3, lines 37-38) while the present invention provides a solution to the very different problem of radiopaquely marking a **polymeric** catheter component. Richter merely discloses a conventional radiopaque marker for a metallic stent and gives no guidance as to the configuration of a radiopaque marker that would be suitable for a polymeric component. In stark contrast thereto, applicants' claimed invention is directed to a radiopaque marker for such application and provides a solution to the problems associated with attempting to mark a polymeric component either by applying a radiopaque marker of sufficient thickness solely by thin film deposition which can damage the polymeric component or by using a conventional machined metal ring which is subject to a thickness minimum (see the specification at page 7, line 21 through page 8, line 12). Such problems are of course not encountered when forming a radiopaque marker on a metallic stent and it is therefore respectfully submitted that the solution to such problem as claimed herein cannot be considered obvious thereover.

Thirdly, it is to be noted that Richter additionally fails to disclose a second layer having a thickness greater than a thickness of the first layer, as is specified in independent claim 1. Richter teaches that the second coating 202 (which constitutes an inner coating relative to the first coating 102, as is explained at column 5, lines 6-9, thus corresponding to applicants' recited "first layer") is the thicker coating, in contrast to applicants' recited claims. As Richter is not concerned with the problem of applying a radiopaque marker to a polymeric material, it is respectfully submitted that applying a first thin layer in order to minimize the impact on the polymeric material followed by the

application of a second thicker layer to the first layer in order to achieve the desired radiopacity cannot be considered obvious over the teachings of the cited reference. For the reasons stated above, it is respectfully submitted that independent claim 1 and all claims depending therefrom effectively avoid anticipation by as well as obviousness in view of Richter.

35 U.S.C. § 102 & 103 Rejections Based on Eckert et al.

Claims 1-3, 6-8, 10, 19-21, 24 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Eckert et al. (U.S. Patent No. 5,858,556). Claims 9, 14-16, 22, 23 and 25 were rejected under 35 U.S.C. 103(a) as being obvious thereover. Applicants respectfully traverse these rejections. Like Richter, Eckert et al. is not directed to a catheter component but rather, to a device that may be delivered **by** or **on** a catheter and further fails to disclose a configuration wherein a radiopaque marker is disposed on a **polymeric** catheter component as is specified in independent claims 1 and 19. Eckert et al. discloses that prior art stents are commonly made of a single material such as stainless steel, tantalum or nitinol (see column 1, lines 43-45) and further discloses a multilayer stent made of a biocompatible material, which is preferably stainless steel (column 3, lines 39-45), as well as a radiopaque material. There is no disclosure in Eckert et al. of any polymeric catheter component. Applicants therefore respectfully submits that independent claims 1 and 19, as well as all claims depending therefrom, clearly avoid anticipation by the cited reference. Moreover, since Eckert is not concerned with the problem of radiopaquely marking a polymeric catheter component, it is respectfully

submitted that a solution to such problem, let alone the solution claimed herein cannot be considered obvious thereover.

Eckert et al. also fails to disclose a second layer having a thickness greater than a thickness of the first layer, as is specified in independent claim 1 and all claims depending therefrom as well as in claim 24. Eckert et al. makes a sole reference to multiple, consecutive radiopaque layers ("thin radiopaque layers 24" at column 4, line 2) but provides no teaching of the thicknesses of the radiopaque layers relative to each other. While the Examiner asserts that "[a] second layer of the same material can be continually deposited, after a first layer is deposited, until the second layer has a thickness greater than that of the first layer" (page 3 of the Office Action), there is no disclosure or suggestion in Eckert et al. to support this statement. Moreover, there is no motivation to do so. It is therefore again submitted that since Eckert is not concerned with the problem of a marking a polymeric catheter component, a solution to such problem, let alone the solution presently claimed cannot be considered obvious thereover.

As to the rejection of claim 26, it is respectfully submitted that the cited reference does not suggest electroplating a radiopaque layer onto a section formed of a **blend** of polymeric material and a radiopaque material. The passage referred to by the Examiner (column 4, lines 50-54) is wholly unrelated to the radiopaque marker. Moreover, the teaching is directed to layers rather than blends. It is therefore respectfully submitted that anticipation as well as obviousness is clearly avoided

35 U.S.C. § 102 Rejections Based on Ragheb et al.

Claims 1, 7, 11 and 26 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Ragheb et al. (U.S. Patent No. 5,873,904). Applicants traverse this rejection on the grounds that Ragheb et al. fails to disclose a second layer of a radiopaque material having a thickness greater than a thickness of a first layer of radiopaque material, as is recited by claim 1. Using the same reasoning asserted with respect to the Eckert et al. rejection, the Examiner states that a second layer of the same material can be continually deposited, after a first layer is deposited, until the second layer has a thickness greater than that of the first layer (page 5 of the Office Action). Ragheb et al., however, provides no disclosure or suggestion to support this statement. There is no discussion in Ragheb et al. relating to the thicknesses of layers of radiopaque materials relative to each other. Thus, applicants respectfully submit that claim 1, as well as its dependent claims 7 and 11, avoid anticipation by Ragheb et al. Moreover, since the cited reference fails to recognize the problem associated with applying a sufficient amount of radiopaque material to a polymeric while avoiding damage thereto, it is respectfully submitted that a solution thereto, let alone the solution that is claimed herein cannot be considered obvious thereover.

As to the rejection of claim 26, it is respectfully submitted that the cited reference does not suggest electroplating a radiopaque layer onto a section formed of a **blend** of polymeric material and a radiopaque material. The passage referred to by the Examiner (column 3, lines 55-60) teaches that the base material may consist of various metals OR

polymers or copolymer plastics. No suggestion is made that radiopaque metal is to be blended with a polymeric material. It is therefore respectfully submitted that anticipation as well as obviousness is effectively avoided.

### 35 U.S.C. § 102 Rejections Based on Leone

Claims 1, 11-13, 17 and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Leone (U.S. Patent No. 5,797,868). Applicants traverse this rejection on the grounds that Leone fails to disclose a radiopaque marker, as is claimed by applicant (see independent claims 1 and 17). Leone is directed to a photodynamic therapy balloon catheter having light reflective material included in the inner member, fluid material and/or balloon member in order to provide uniform illumination (see Abstract). Leone does not relate to a radiopaque marker as does the present application. As is well known to one skilled in the art, the use of reflective material in a catheter component does not inherently create a radiopaque marker. As is explained in applicant's specification at page 3, lines 15-17, a radiopaque marker can be seen under x-ray or fluoroscopy imaging. Leone provides no disclosure that its balloon catheter having light reflective material is a radiopaque marker. Page 4, lines 20-21 of the specification further explains that visibility under fluoroscopy or x-ray requires sufficient thickness of the marker. Thus, the radiopacity of marker depends not only on the radiopaque material selected, but also on the thickness of the radiopaque material. It is therefore respectfully submitted that anticipation is effectively avoided. Moreover, since rendering a component radiopaque presents a very different problem than merely rendering it reflective and since this

reference is not concerned with the problem of doing so without damaging an underlying polymeric component, it is respectfully submitted that a solution thereto, let alone the solution claimed herein cannot be considered obvious thereover.

It is also to be noted that Leone does not disclose a first and second layer of radiopaque material, as is recited in claims 1, 12 and 18. Leone further does not disclose that the second layer is on the first layer or that the second layer has a thickness greater than a thickness of the first layer, also claimed by applicant. For support, the Office at page 6 of the Office Action refers to column 5, lines 12-17, which states that the reflective material may be compounded with the material of balloon member either coated on the balloon member or loaded into the balloon material. This provides no disclosure or suggestion of a first layer and a second layer of radiopaque material, as is claimed by applicant. For the foregoing reasons, applicants submit that independent claims 1 and 17 and all claims depending therefrom are allowable over Leone.

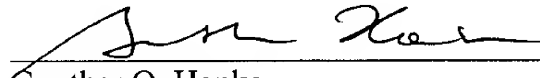
CONCLUSION

In light of the above amendments and remarks, applicants earnestly believe the application to be allowable over the cited art and respectfully request that it be passed to issue.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

The claims have been amended as follows

1) (Amended) An intraluminal catheter having a polymeric component having at least one radiopaque marker, the radiopaque marker comprising:

- a) a first layer of radiopaque material; and
- b) a second layer of radiopaque material on the first layer, having a thickness greater than a thickness of the first layer.

2) (Amended) The catheter of claim 1 wherein the first layer of radiopaque material comprises a deposited layer of radiopaque material on an outer surface of the polymeric catheter component, and the second layer of radiopaque material comprises an electroplated layer of radiopaque material on an outer surface of the first layer of radiopaque material.

9) (Amended) The catheter of claim 7 wherein the polymeric catheter component comprises a first section longitudinally spaced from a second section adjacent thereto, and the first layer of radiopaque material is joined to and extends between the longitudinally spaced sections.

10) (Amended) The catheter of claim 1 wherein the polymeric catheter component is a catheter shaft.

11) (Amended) The catheter of claim 1 wherein the polymeric catheter component is an inflatable balloon.

19) (Amended) A method of making a radiopaque marker for a polymeric catheter component, comprising:

a) depositing a first layer of radiopaque material onto at least a section of the polymeric catheter component; and

b) electroplating a second layer of radiopaque material onto an outer surface of the first layer of radiopaque material.

20) (Amended) The method of claim 19 including depositing the first layer of radiopaque material onto a section of the polymeric catheter component having a length substantially less than a length of the polymeric catheter component.

<sup>23</sup>  
~~21~~ (Amended) The method of claim 19 wherein the polymeric catheter component is a balloon and including electroplating onto the first layer a thicker layer of radiopaque material than the first layer of radiopaque material, to form the second layer.

22) (Amended) The method of claim 19 [29] wherein the polymeric catheter component is a catheter shaft and including electroplating onto the first layer a thicker layer of radiopaque material than the first layer of radiopaque material, to form the second layer.